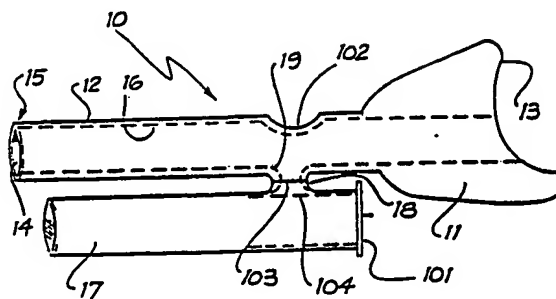




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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**(54) Title:** MID STREAM URINE DEVICE**(57) Abstract**

Mid stream devices for use by a standing, sitting, squatting or generally supine female or male are disclosed. The devices direct a urine stream a satisfactory distance away from the female or male and permit collection of a mid stream urine sample from the stream. The device for the female includes a body having a discharge passage therethrough for receiving and discharging the stream from an ostium urethrae externum feminae the body having a urine stream receiving portion defining one end of the passage, disposed in a skin abutting end operatively coupled to or integral with the body, a urine stream exit portion defining the other end of the passage, disposed in a urine discharge end portion operatively coupled to or integral with the body and a mid stream sampling port disposed intermediate to the receiving portion and the exit portion of the discharge passage. The device for the male includes a body having a discharge passage therethrough for receiving and discharging the stream from an ostium urethrae externum masculinae the body having a urine stream receiving portion defining one end of the passage, disposed in a penis receiving end operatively coupled to or integral with the body, a urine stream exit portion defining the other end of the passage, disposed in a urine discharge end portion operatively coupled to or integral with the body and a mid stream sampling port disposed intermediate to the receiving portion and the exit portion of the discharge passage.

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MID STREAM URINE DEVICETECHNICAL FIELD

This invention relates to a mid stream urine device for use by a standing, sitting, squatting or generally supine female to direct a urine stream a satisfactory distance away from the female and for collecting a mid stream urine sample from the stream and to a mid stream urine device for use by a standing, sitting, squatting or generally supine male to direct a urine stream a satisfactory distance away from the male and for collecting a mid stream urine sample from the stream.

BACKGROUND ART

Samples of urine from both males and females for scientific and medical testing are preferably taken a short time after commencement of urination to minimize the chance of false test results due to contamination by residual urine. For females mid stream urine samples can be especially difficult to obtain due to the position and geometrical shape of the female genital region. Obtaining a mid stream urine sample from a female can be especially troublesome in circumstances when such a sample is particularly required, for example when:

- (i) When there are wounds, sores, lesions or the like in the female genital region;
- (ii) during outbreaks of thrush and herpes and other genital infections which occur in females;
- (iii) during a post natal period; and
- (iv) following a period immediately after surgery on the female genital region;
- (v) during a female's menstrual period; and
- (vi) in hospitals and nursing homes urinating for bedridden female patients is difficult since a bedpan has to be inserted underneath the

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patient's genital region.

It follows that there is a need for a urine device for use by a standing, sitting, squatting or generally supine female to direct a urine stream a satisfactory distance away from the female, typically leaving minimal or substantially no residual urine in the genital region after urination, and for collecting a mid stream urine sample from the stream.

#### OBJECTS OF INVENTION

It is therefore an object of this invention to provide a mid stream urine device for use by a standing, sitting, squatting or generally supine female to direct a urine stream a satisfactory distance away from the female and for collecting a mid stream urine sample from the stream.

Another object is to provide a mid stream urine device for use by a standing, sitting, squatting or generally supine male to direct a urine stream a satisfactory distance away from the male and for collecting a mid stream urine sample from the stream.

#### DISCLOSURE OF INVENTION

Throughout this specification it should be understood that the term "manually operable urine valve" includes both mechanical devices such as stop-cocks and clamps as well as any combination of parts of the invention or its equivalents which effect stoppage of, or initiation of urine flow.

According to a first embodiment of this invention there is provided a mid stream urine device for use by a standing, sitting, squatting or generally supine female to direct a urine stream a satisfactory distance away from the female and for collecting a mid stream urine sample from the stream, the device comprising:

a body having a discharge passage therethrough for receiving and discharging the stream from an ostium urethrae externum feminae the body having:

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a urine stream receiving portion defining one end of the passage, disposed in a skin abutting end operatively coupled to or integral with the body;

a urine stream exit portion defining the other end of the passage, disposed in a urine discharge end portion operatively coupled to or integral with the body; and

a mid stream sampling port disposed intermediate to the receiving portion and the exit portion of the discharge passage.

According to a second embodiment of this invention there is provided a mid stream urine device for use by a standing, sitting, squatting or generally supine male to direct a urine stream a satisfactory distance away from the male and for collecting a mid stream urine sample from the stream, the device comprising:

a body having a discharge passage therethrough for receiving and discharging the stream from an ostium urethrae externum masculinae the body having:

a urine stream receiving portion defining one end of the passage, disposed in a penis receiving end operatively coupled to or integral with the body;

a urine stream exit portion defining the other end of the passage, disposed in a urine discharge end portion operatively coupled to or integral with the body; and

a mid stream sampling port disposed intermediate to the receiving portion and the exit portion of the discharge passage.

Typically, the mid stream urine device includes a urine sample container having a container coupling engagable with the port.

Alternatively, the mid stream urine device includes a urine sample container;

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a cap to engage the container the cap having an aperture and a container coupling engagable with the port operatively associated with the cap aperture; and

a cap to seal the cap aperture before and after use.

Typically, the port and/or coupling has a breakable seal.

Alternatively, the mid stream urine device can be in combination with a breakable seal for sealing the port and/or a breakable seal for sealing the coupling.

In one arrangement the port has a breakable seal and the coupling has means to break the seal on engagement with the port.

in another arrangement the coupling has a breakable seal and the port has means to break the seal on engagement with the coupling.

In another alternative arrangement the mid stream urine device includes a urine sample container, a cap to seal the container the cap having a container coupling engagable with the port and a manually operable urine valve operatively associated with the container coupling wherein on opening the valve a mid stream urine sample of the stream passes from the discharge passage into the container via the port.

Preferably the urine valve is integral with the container coupling.

Alternatively, the urine valve may be integral with the port.

Typically, the mid stream urine device includes a coupling tube operatively associated with the valve to interconnect the urine valve and the port.

Generally the body has a thread coupling in the immediate vicinity of the port and the urine valve has a complementary thread coupling whereby the valve is threadably couplable to the body whereby to communicate with the port.

Generally the mid stream sample container has an automatic or a

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manually operable air release valve disposed in the upper portion of container for releasing air as the container fills with urine.

The mid stream sample container may contain test strips or an indicator which turn an appropriate colour on contacting urine which contains matter being tested. The mid stream sample container may be transparent to enable one to determine whether a test strip therein has changed to a particular colour without opening the container.

In one preferred form the mid stream sample container can have both an automatic or manually operable air release valve disposed on top of the container to release air as the container fills with urine and an automatic or manually operable urine valve operatively associated with or integral with the coupling means. Alternatively an integral manually operable rotatable gate valve can be operatively associated with the container whereby the valve can be operated by a user to release air from the top of the container while simultaneously permitting to urine to enter the container. Typically the container is a cylindrical phial which has a urine capacity of 4ml to 50ml, more preferably 5 to 35ml and even more preferably 8 to 15ml.

The urine valve may be integral with the container and attached to the body by a flexible or non flexible coupling tube which can be readily cut or manually torn to separate the container, the valve and that portion of the coupling means operatively associated with or integral with the valve and the container from the body. Alternatively, the urine valve can be integral with the container and attached to the body by a screw thread coupling or a snap fit coupling which can be manually unscrewed or decoupled to separate the container, the valve and that portion of the coupling means operatively associated with or integral with the valve and the container from the body. A further alternative can be attached to the

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body and to the container by a flexible or non flexible coupling tube. In yet another embodiment, the valve may be formed by the port in co-operation with a flexible portion of the container, whereby the valve is operated by manually depressing the flexible portion against the sampling passage.

The discharge passage may have a urine deflector disposed therein so as to deflect a portion of urine flowing through the discharge passage into the port.

Generally, the plug is not removable from the cap aperture after insertion therein and the cap and/or container has a tamper indicator to indicate whether the container has been opened.

Typically, the urine discharge end portion has a tube engaging lug which defines the urine discharge end.

Preferably the urine discharge end portion has a tube engaging lug or dimple which defines the urine discharge end. The lug or dimple can be coupled to a urine sample container by means of a flexible tube.

Generally, the mid stream urine device further includes a urine collector container and a tube interconnecting the lug and the collector container.

In another preferred form, the mid stream urine device includes a removable plug which is adapted to seal both the port and an aperture in the cap of the container when the container is not coupled to the port.

The skin abutting end is typically adapted to abut the genital region of a user adjacent to and surrounding the ostium of the user to provide a substantial seal against leakage of urine directed into the receiving perforation when the mid stream urine device is disposed in an operative position abutting the genital region adjacent the ostium of the user.

In one preferred form the mid stream urine device the body includes a front portion and a back portion. The discharge passage extends through the



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front and back portions. The front portion is adjacent and integral with the skin abutting end and is substantially pear-shaped, spherical, cylindrical, square, elliptical, rectangular, V-shaped, U-shaped, cup-shaped, ovoid, distorted pear shape or other like shapes for receiving urine from an ostium through the urine receiving perforation which in turn is defined by a distorted, substantially U-shaped or curved-shaped skin abutting end integral with the body. The shape of the 'U' is such that it is adapted to abut a female genital region adjacent to and surrounding the ostium to provide a substantial seal against leakage of urine directed into the perforation. Preferably the shape of the front portion prevents or minimises splash back of urine back through the urine receiving aperture. The back portion is a tube which is integral/detachable with the front portion. The tube has an integral urine discharge end portion.

The discharge passage is of such a diameter that it has sufficient capacity to permit discharge of urine flowing therethrough at a high discharge rate.

The front portion can be made from non flexible material or material which is flexible, resilient yet relatively stiff. The non flexible material and flexible material should be preferably resistant to degradation/attack by human urine. Suitable non flexible materials include ceramics, glass, teflon, perspex, stainless steel and various plastics such as polyethylene, polyvinylchloride and polypropylene and thermoplastics. Suitable flexible materials include natural rubber, synthetic rubber, rubber composition, certain thermoplastics, e.g. DELRIN (trade mark) nylon and plastics such as polyethylene polyvinylchloride and polypropylene. The front portion can also be fabricated from a biodegradable polymer such as BIOPOL (trade mark) which is marketed by ICI.

The integral/detachable tube can be made from non flexible material

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or material which is flexible, resilient yet relatively stiff, similar to that of the mid stream urine device above. However, the tube can also be made from flexible, relatively stiff material which retains a tubular shape but is not necessarily resilient such that if the tube is bent to direct urine discharged therethrough to a certain location, for example, then the tube is not required to return to its former shape. In a particularly preferred option the tube includes a non resilient flexible portion in relation to which the tube can be bent to direct urine discharged therethrough to a desired location.

The mid stream urine device can be made from a non flexible/flexible yet relatively stiff material(s), as indicated above, which is disposable or non disposable.

It is preferred that the skin abutting end is dimensioned to fit over an ostium urethrae externum feminae of a female greater than 12 years.

A preferred mid stream urine device according to the invention when in use by a user directs urine away from the genital region adjacent to ostium urethrae externum feminae leaving minimal residual urine in the genital region. Thus use of a mid stream urine device of the invention helps to minimise irritation of the female genital region by residual urine when there are wounds, sores, lesions or the like present; during outbreaks of thrush and herpes and other genital infections which occur in females; during the post natal period particularly when the female genital region has been damaged during childbirth; and during a recovery period immediately following surgery on the female genital region. Use of a mid stream urine device of the invention is especially advantageous during the post natal period of a female who during childbirth has had an episiotomy including minor tears and lesions since contact of urine with the damaged regions tends to result in excruciating pain. In addition since there is

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little residual urine after use of the mid stream urine device a tampon does not have to be replaced every time a menstruating female urinates. A mid stream urine device can be used by bedridden female patients to assist in urination into a bedpan. In a mid stream urine device of the invention the tube can be used to direct the urine emanating therefrom to a suitable location, particularly if the tube is flexible, has an integral flexible portion associated with the tube or is an integral part of the tube. The mid stream urine device of the invention can readily be used to providing urine samples, e.g. in a hospital, surgery, etc. in a bottle. The use of a mid stream urine device is especially advantageous for collecting midstream urine samples since a patient can avoid fingernail, pubic hair and skin contact with the top of the sample bottle and thus reduce the possibility of contamination of the urine sample. The use of a mid stream urine device for females protects a substantial portion of the vagina from urine contact. Use of a mid stream urine device of the invention can in certain instances avoid the need for catheterization. For example, where there has been an operation in the vicinity of the genital region, e.g. the removal of a coccyx contact of urine with that region during the post operative period can result in an infection. When that occurs a catheter is often inserted through the urethra to the bladder however this insertion can itself result in an infection in the bladder region. Use of a mid stream urine device would minimise urine contact with the genital region and thus reduce the risk of the initial infection. Embodiments of the invention can also be used by females without having to sit down on toilet seats, e.g. in a public toilet or when camping, fishing, hiking, etc.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention are now described with reference to the following drawings in which:-

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Fig. 1 is a side view of one embodiment of a mid stream urine device of the invention having an integral manually operable air release and rotatable urine gate valve operatively associated with the container;

Fig. 2 is a side view of another embodiment of a mid stream urine device of the invention having manually rotatable urine valve air release integral with a coupling tube between the body and the sample of the container;

Fig. 3 is a side view of a further embodiment of a mid stream urine device of the invention having a body having a front portion and a back portion which can be decoupled from each other;

Fig. 4 is a side view of the mid stream urine device of Fig. 3 coupled to a urine collector container;

Figs. 5, 6 and 7 are side, front and top views of the front portion of the mid stream urine device of Fig. 3;

Figs. 8a, 8b and 8c are side, front and bottom views of the front portion of the mid stream urine device of Fig. 3 showing preferred dimensions;

Fig. 9 is a side view of a alternative front portion for use with the mid stream urine device of Fig. 3;

Fig. 10 is a side view of another front portion for use with the mid stream urine device of Fig. 3;

Fig. 11 illustrates a further alternative front portion for use with the mid stream urine device of Fig. 3. Fig. 11 shows the following views: (a) perspective view; (b) left side view; (c) front view; (d) back view; (e) plan view; and (f) inverted plan view;

Fig. 12 illustrates yet a further alternative front portion for use with the mid stream urine device of Fig. 3. Fig. 12 shows the following views:

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(a) perspective view; (b) left side view; (c) front view; (d) back view; (e) plan view; and (f) inverted plan view;

Fig. 13 illustrates yet another further alternative front portion for use with the mid stream urine device of Fig. 3. Fig. 13 shows the following views:

(a) perspective view; (b) left side view; (c) front view; (d) back view; (e) plan view; and (f) inverted plan view;

Fig. 14 illustrates a side view of a manually operable gate valve for use in the mid stream urine device shown in Fig. 1;

Fig. 15 is a side elevation showing an alternate embodiment of the present invention;

Fig. 16 is a top plan view of the device shown in Fig. 15;

Fig. 17 is a left side elevation of the device shown in Fig. 15;

Fig. 18 is a cross sectional view of the container coupling fitment used in conjunction with the device shown in Fig. 15;

Fig. 19 is a cross sectional view of the cap used to seal both the container coupling fitment and the port of mid stream sampling passage of the device shown in Fig. 15.

Fig. 20A is an exploded side elevation showing a further alternate embodiment of the present invention;

Fig. 20B is a bottom plan view of a mid stream urine device shown in Fig. 20A;

Fig. 20C is a front view the device shown in Fig. 20B;

Fig. 20D is a cross sectional partially exploded view of an embodiment of Fig. 20A;

Fig. 20E is a partial cross sectional view along AA of Fig. 20G showing the port of the mid stream urine device of Fig. 20A partially inserted into the aperture of the coupling in the cap of Fig. 20A;

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Fig. 20F depicts a partial cross sectional view along AA of Fig. 20G showing the port of the mid stream urine device of Fig. 20A fully inserted into the aperture of the coupling in the cap of Fig. 20A;

Fig. 20G depicts a plan view of the coupling in the cap of Fig. 20A;

Fig. 21A is an exploded side elevation showing a further alternate embodiment of the present invention;

Fig. 21B is a bottom plan view of a mid stream urine device shown in Fig. 21A;

Fig. 21C is a front view the device shown in Fig. 21B;

Fig. 21D is a cross sectional view of a partly assembled embodiment of Fig. 21A;

Fig. 21E is a partial cross sectional view along AA of Fig. 21G showing the port of the mid stream urine device of Fig. 21A partially inserted into the aperture of the coupling in the cap of Fig. 21A;

Fig. 21F depicts a partial cross sectional view along AA of Fig. 21G showing the port of the mid stream urine device of Fig. 21A fully inserted into the aperture of the coupling in the cap of Fig. 21A; and

Fig. 21G depicts a plan view of the coupling in the cap of Fig. 21A.

#### BEST MODE AND OTHER MODES FOR CARRYING OUT THE INVENTION

Referring to Fig. 1 a mid stream urine device 10 for use by a standing, sitting, squatting or generally supine female to direct a urine stream a satisfactory distance away from the female and for collecting a mid stream urine sample from the stream, which device includes a body having a front portion 11 integral with a back portion comprising tube 12. A discharge passage 16 extends through front portion 11 and tube 12 for receiving and discharging the stream from an ostium urethrae externum feminae via a urine stream receiving perforation defining one end of the passage, disposed in a skin abutting end 13 integral with front portion 11

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and a urine stream exit perforation 14 defining the other end of the passage, disposed in a urine discharge end portion 15 integral with tube 12. Mid-stream sample container 17 is coupled to tube 12 via coupling tube 18. Coupling tube 18 has a urine mid stream sampling passage 19 therethrough which couples discharge passage 16 to container 17 via a manually operable rotatable gate valve 101 as shown in Fig. 1. Gate valve 101 is operatively associated with container 17 and can be utilized to release air from the top of container 17 while simultaneously permitting urine to enter container 17. Discharge passage 16 has a urine deflector lug portion 102 disposed opposite sampling passage 19 to deflect a portion of urine flowing through discharge passage 16 into sampling passage 19 and into container 17 when valve 101 is open. Coupling tube 18 also has a crease 103 whereby container 17 and valve 101 and that portion of coupling tube 18 extending between crease 103 and container 18 can be separated as a whole from tube 12 by manually tearing coupling tube 18 along crease 103. Whilst container 17 is depicted in Fig. 1 as being coupled to the bottom of tube 12 it will be appreciated that container 17 can be coupled to tube 12 at an alternative location such as at the side of tube 12 or at a location between the side and bottom of tube 12 or at any other convenient location.

In use a female user manually locates device 10 so that discharge passage 16 is adjacent to and surrounds the user's ostium and a seal is formed by manually pressing abutting end 13 against skin surrounding the ostium. The user then discharges urine into device 10 so that it passes through discharge passage 16 and exits out of exit perforation 14. Gate valve 101 which is initially closed, is rotated to align a urine valve entry perforation in wall 104 of valve 101 with sampling passage 19, some 3 to 8 seconds after the user has commenced urinating to permit a portion of

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urine passing through discharge passage 16 to flow into container 17 via sampling passage 19. At the same time as valve 101 is rotated it is pulled partially out of container 17 to expose at least one air release perforation in wall 104 to allow air to escape from container 17 as it fills with urine. After container 17 is filled with urine the user pushes valve 101 back into container 17 and rotates valve 101 to seal the urine sample in container 17. After urination container 17 can be separated from tube 12 by manually tearing or scissoring coupling tube 18 along crease 103. After separating container 17 from tube 12 valve 101 can be pulled out of container 17 and a urine sample can be pipetted from open container 17 and used for testing. Container 17 and the other portion of device 10 can be disposed.

Other embodiments of mid stream urine devices which can be similarly utilized are described briefly below:-

In Fig. 2 mid stream urine device 20 is similar to device 10 in Fig. 1 except container 21 is coupled to tube 22 and discharge passage 23 via coupling tube 24 which has a sampling passage 27 which extends therethrough and an integral manually rotatable valve 25. In addition container 21 has a push-pull air release valve 26.

In Fig. 3 mid stream urine device 30 is similar to device 10 in Fig. 1 except front portion 31 is releasably coupled with back portion comprising tube 32. Device 30 has the advantage that front portion 31 can be retained and therefore be custom made to suit the user, while tube 32 with attached sample container 33 are disposable.

In Fig. 4 mid stream urine device 40 is similar to device 30 in Fig. 3 except back portion comprising tube 41 has tube retaining external bumps 42 and 43 disposed in the vicinity of the distal end of tube 41. Device 40 can be readily coupled to urine collector container 44 via coupling tube 45



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as illustrated.

In Figs. 5, 6 and 7 depict side 50, front 60 and top 70 views of a front portion 31 of mid stream urine device 30 depicted in Fig 3.

In Fig. 8a preferred dimensions of side 50 shown in Fig. 5 are as follows:

$a = 14\text{mm}$ ,  $c = 30\text{mm}$ ,  $d = 35\text{mm}$ ,  $e = 39\text{mm}$ ,  $f = 20\text{mm}$ .

In Fig. 8b preferred dimensions of front 60 shown in Fig. 6 are as follows:

$g = 35\text{mm}$ ,  $g' = 30\text{mm}$ ,  $g'' = 28\text{mm}$  and  $g''' = 25\text{mm}$ .

In Fig. 8c preferred dimensions of a bottom view of a front portion 31 of mid stream urine device 30 depicted in Fig. 3 are as follows:

$h = 14\text{mm}$ ,  $i = 59\text{mm}$  and  $j = 22\text{mm}$ .

In Fig. 9 an alternative front portion 90 for use instead of front portion 31 in mid stream urine device 30 is depicted. Front portion 90 has a flexible joint 91 which can be resilient or non resilient. Front end 92 can be bent about flexible joint 91 thereby facilitating manipulation of the angle between tube 32 and front portion 90 by a user to enable the user to easily direct a urine stream a satisfactory distance away from the user.

In Fig. 10 an alternative front portion 110 for use instead of front portion 31 in mid stream urine device 30 is depicted. Front portion 110 has a flexible coupling tube 112 which can be resilient or non resilient which couples a linking tube 113 to front portion 111. Front end 111 can be bent about flexible coupling tube 112 thereby facilitating manipulation of the angle between tube 32 and front portion 110 by a user to enable the user to easily direct a urine stream a satisfactory distance away from the user.

Figs. 11(a) - (f), 12(a) - (f) and 13(a) - (f) depict various views of three different alternative front portions for use instead of front

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portion 31 in mid stream urine device 30.

Fig. 14 depicts a manually operable gate valve 101 for use in mid stream urine device 10 shown in Fig. 1. Valve 101 has a urine valve entry perforation 140 and air release perforations 141 and 142 in wall 104. Valve 101 also has a cap 143 on which is mounted a pin 144. Cap 143 and/or pin 144 can be grasped by a user so that the user can manipulate the position of valve 101 when it is disposed in the top of container 17, in a manner which has been already described in connection with device 10 of Fig. 1.

Fig. 15 depicts an alternate preferred form of the invention 200. In this embodiment the body 201 includes a skin abutting end 202 having a curved skin contacting region 203. The skin abutting end has a urine receiving opening or portion 204 defining one end of a central passage 205. As shown in Fig. 17, the contacting region 203 and receiving opening 204 are generally elliptical. The other end of the central passage 205 defines a urine discharge portion 206. Because the discharge portion is smaller in diameter than the receiving portion, the exterior aspect 207 of the body is seen to taper as shown in Figs. 15 and 16. Between the receiving portion 204 and the discharge portion 206, a mid stream sampling passage 208 intersects and joins the central passage 205 at about a right angle. The distal end of the sampling passage forms a port 209 which is sealable by the cap 250 shown in Fig. 19. The port also forms a body side coupling to a sample container 220 as shown in Fig. 18.

The sample container 220 is understood to be any flexible receptacle, bag or appliance, sealed but for a container coupling 230. The container coupling includes a flange 231 for attachment to the container, an inlet passage 232 and an enlarged portion 233 which frictionally seals against the exterior of the sampling passage port 209. A chamber 234 leads from

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the inlet passage to the enlarged portion 233. The container coupling is also sealable by the cap 250 shown in Fig. 19.

The cap 250 includes a rim 251, a recess 252 and side walls 253 having an exterior surface 254. The cap is sealed by a bottom wall 255. Thus, the recess and the exterior surface of the side walls form two distinct sealing regions of different diameters, in essence a plug and a lid, thus suitable for sealing the different sized openings of the container coupling 230 and the inlet passage opening 236.

The operational procedure for the collection device shown in Figs. 15 to 19 is as follows. For ordinary urinary discharge to a waste receptacle, the device is used with the cap 250 placed over or into the sample passageway 208. This has the effect of diverting all flow through the discharge portion 206. If a sample is to be taken during a discharge the sample container 220 is fitted to the port 209 instead of the cap 250. The container is selectively isolated from urine flow by pressing the container material 235 opposite the coupling 230 against the inlet passage opening 236. This seals the container. Mid-stream filling is accomplished when pressure is relieved from the container material 235. If the container overflows, excess urine is carried away through the discharge portion 206. When discharge is complete, the entire device with container attached is removed from the user. The container is removed by straddling the container coupling 230 with the index and middle fingers, then sealed by pressing with the thumb against the container 235 over the inlet passage opening 236 and pulling the sealed container away from the port 209. The cap 250 can then be placed over the container coupling 230. The container contents can be accessed by either removing the cap or disrupting the container material such as by cutting or piercing.

Referring to Fig. 20A a mid stream urine device 300 for use by a

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standing, sitting, squatting or generally supine female to direct a urine stream a satisfactory distance away from the female and for collecting a mid stream urine sample from the stream, includes a body 301 having a discharge passage 302 therethrough for receiving and discharging the stream from an ostium urethrae externum feminae. Device 300 has a urine stream receiving portion 303 defining one end of passage 302 disposed in a skin abutting end 304 which is integral with body 301. A urine stream exit portion 306 defines the other end of passage 302 and is disposed in a urine discharge end portion 305 which is integral with body 301. Body 301 has a mid stream sampling port 307 disposed intermediate to receiving portion 303 and exit portion 306. Coupling 308 which defines aperture 309 in cap 310 is dimensioned to receive port 307. Aperture 309 has breakable seal 318 spanning across the width of aperture 309, seal 318 having protrusions 317 which engage the walls of port 307 when port 307 is inserted into aperture 309. Cap 310 fits onto the top of urine sample container 311 so as to engage tamper proof indicator ring 319 which has shearable lug 320. Lug 320 engages the bottom rim of cap 310 on engaging cap 310 with container 311 in such a way that on removing cap 310, lug 320 shears at least partially from ring 319 thus indicating that container 311 has been tampered. Cap 312 seals coupling 308 when not in use. Container 311 has a recessed bottom 313, the recess being defined by walls 314 which extend down from bottom 313. The recess in the bottom of container 311 enables sample containers to be stacked on one another. Fig. 20A also depicts tube 315 which fits over end portion 305 and the other end of tube 315 can be coupled to a urine collector container.

Fig. 20B which depicts a bottom plan view of device 300 in Fig. 20A clearly shows that port 307 defines an aperture 308 through which a mid stream urine sample can be collected. Shown in Fig. 20A and 20B are

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preferred dimension of mid stream urine device 300.

Fig. 20C which depicts a front view of device 300 in Fig. 20A clearly depicts urine stream receiving portion 303 and skin abutting end 304.

Fig. 20D depicts a cross sectional partially exploded view of the embodiment of Fig. 20A. In Fig. 20D cap 310 is located on container 311.

Fig. 20E depicts a partial cross sectional view along AA of Fig. 20G showing port 307 of device 300 of Fig. 20A partially inserted into aperture 309 of coupling 308 in cap 310 of Fig. 20A. Port 307 has grooves 322 for venting air. Aperture 309 has breakable seal 318 spanning across the width of aperture 309, seal 318 having protrusions 317 which engage the walls of port 307 when port 307 is inserted into aperture 309. Protrusions 317 are disposed on either side of separating strip 319 via folding portions 320, and are linked to coupling 308 by breakable strip 321.

Fig. 20F depicts a partial cross sectional view along AA of Fig. 20G showing port 307 of device 300 of Fig. 20A fully inserted into aperture 309 of coupling 308 in cap 310 of Fig. 20A. Protrusions 317 are disposed on either side of separating strip 319 and folded about folding portions 320, and strip 321 has been broken away from coupling 308 by engagement of protrusions 317 with port 307.

Fig. 20G depicts a plan view of coupling 308 in cap 310 of Fig. 20A. This figure depicts four protrusions 317 disposed on breakable seal 318.

In use a female user manually locates device 300 so that discharge passage 302 is adjacent to and surrounds the user's ostium and a seal is formed by manually pressing end 304 against skin surrounding the ostium. Port 307 is partially inserted into aperture 309 in coupling 308 of cap 310 which is engaged to container 311 in such a way so as not to break breakable seal 318. The user then discharges urine into device 300 so that it passes through discharge passage 302 whereby initially urine exits out

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of exit portion 306. Port 307 is then fully inserted into aperture 309 so as to break seal 318. A portion of urine passing through discharge passage 302 flows into container 311 via aperture 316 in port 307 and aperture 309 in coupling 308, air being automatically vented from container 311 by grooves 322. After container 311 is filled with urine the user decouples cap 310 from port 307 without removing it from container 311. Cap 312 is then used to close coupling 308. At a later stage a mid stream urine sample can be taken from container 311 and used for testing.

Referring to Fig. 21A a mid stream urine device 400 for use by a standing, sitting, squatting or generally supine male to direct a urine stream a satisfactory distance away from the male and for collecting a mid stream urine sample from the stream, includes a body 401 having a discharge passage 402 therethrough for receiving and discharging the stream from an ostium urethrae externum masculinae. Device 400 has a urine stream receiving portion 403 defining one end of passage 402 disposed in a skin abutting end 404 which is integral with body 401. A urine stream exit portion 406 defines the other end of passage 402 and is disposed in a urine discharge end portion 405 which is integral with body 401. Body 401 has a mid stream sampling port 407 disposed intermediate to receiving portion 403 and exit portion 406. Cap container coupling 408 which defines aperture 409 in cap 410 is dimensioned to receive port 407. Aperture 409 has breakable seal 418 spanning across the width of aperture 409, seal 418 having protrusions 417 which engage the walls of port 407 when port 407 is inserted into aperture 409. Cap 410 fits onto the top of urine sample container 411. Cap 412 seals coupling 408 when not in use. Container 411 has a recess bottom 413, the recess being defined by walls 414 which extend down from bottom 413. The recess in the bottom of container 411 enables sample containers to be stacked on top of one another. Fig. 21A also

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depicts a tube 415 which fits over end portion 405 and the other end of tube 415 can be coupled to a urine collector container.

Fig. 21B which depicts a bottom plan view of device 400 in Fig. 21A clearly shows that port 407 defines an aperture 408 through which a mid stream urine sample can be collected.

Fig. 21C which depicts a front view of device 400 in Fig. 21A clearly depicts urine stream receiving portion 403 and skin abutting end 404.

Fig. 21D depicts a cross sectional partially exploded view of the embodiment of Fig. 21A. In Fig. 21D cap 410 is located on container 411.

Fig. 21E depicts a partial cross sectional view along AA of Fig. 21G showing port 407 of device 400 of Fig. 21A partially inserted into aperture 409 of coupling 408 in cap 410 of Fig. 21A so as not to break seal 418. Port 407 has grooves 422 for venting air. Aperture 409 has breakable seal 418 spanning across the width of aperture 409, seal 418 having protrusions 417 which engage the walls of port 407 when port 407 is inserted into aperture 409. Protrusions 417 are disposed on either side of separating strip 419 via folding portions 420, and are linked to coupling 408 by breakable strip 421.

Fig. 21F depicts a partial cross sectional view along AA of Fig. 21G showing port 407 of device 400 of Fig. 21A fully inserted into aperture 409 of coupling 408 in cap 410 of Fig. 21A. Protrusions 417 are disposed on either side of separating strip 419 and folded about folding portions 420, and strip 421 has been broken away from coupling 408 by engagement of protrusions 417 with port 407.

Fig. 21G depicts a plan view of coupling 408 in cap 410 of Fig. 21A. This figure depicts four protrusions 417 disposed on breakable seal 418.

In use a male user manually locates device 400 by placing his penis in receiving portion 403 so that discharge passage 402 is adjacent to and

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surrounds at least a portion of the user's penis and thus the user's ostium. Port 407 is partially inserted into aperture 409 in coupling 408 of cap 410 which is engaged to container 411 in such a way so as not to break breakable seal 418. The user then discharges urine into device 400 so that it passes through discharge passage 402 whereby initially urine exits out of exit portion 406. Port 407 is then fully inserted into aperture 409 so as to break seal 418. A portion of urine passing through discharge passage 402 flows into container 411 via aperture 416 in port 407 and aperture 409 in coupling 408, air being automatically vented from container 411 by grooves 422. After container 411 is filled with urine the user decouples cap 410 from port 407 without removing it from container 411. Cap 412 is then used to close coupling 408. At a later stage a mid stream urine sample can be taken from container 411 and used for testing.

#### INDUSTRIAL APPLICABILITY

A mid stream urine device of the invention for use by a female can be readily used to collect a mid stream urine sample from the female. A mid stream urine device of the invention for use by a male can be readily used to collect a mid stream urine sample from the male.



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CLAIMS

1. A mid stream urine device for use by a standing, sitting, squatting or generally supine female to direct a urine stream a satisfactory distance away from said female and for collecting a mid stream urine sample from said stream, said device comprising:

a body having a discharge passage therethrough for receiving and discharging said stream from an ostium urethrae externum feminae said body having:

a urine stream receiving portion defining one end of said passage, disposed in a skin abutting end operatively coupled to or integral with said body;

a urine stream exit portion defining the other end of said passage, disposed in a urine discharge end portion operatively coupled to or integral with said body; and

a mid stream sampling port disposed intermediate to said receiving portion and said exit portion of said discharge passage.

2. A mid stream urine device of claim 1 further comprising a cap adapted to seal said port.

3. A mid stream urine device of claim 1 further comprising a urine sample container having a container coupling engagable with said port.

4. A mid stream urine device of claim 1 further comprising:

a urine sample container;

a cap to engage said container said cap having an aperture and a container coupling engagable with said port operatively associated with said cap aperture; and

a cap to seal said cap aperture before and after use.

5. A mid stream urine device of claim 1 further comprising:

a urine sample container;

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a cap to seal said container said cap having a container coupling engagable with said port; and

a urine valve operatively associated with said container coupling wherein on opening said valve a mid stream urine sample of said stream passes from said discharge passage into said container via said port.

6. A mid stream urine device of claim 3, 4 or 5 wherein said sample container has an air release valve disposed in said upper portion of container for releasing air as said container fills with urine.
7. A mid stream urine device of claim 1 wherein said discharge passage has a urine deflector disposed therein so as to deflect a portion of urine flowing through said discharge passage into said port.
8. A mid stream urine device of claim 5 wherein said urine valve is integral with said container coupling.
9. A mid stream urine device of claim 8 further comprising a coupling tube operatively associated with said valve to interconnect said urine valve and said port.
10. A mid stream urine device of claim 8 wherein said body has a thread coupling in said immediate vicinity of said port and said urine valve has a complementary thread coupling whereby said valve is threadably couplable to said body whereby to communicate with said port.
11. A mid stream urine device of claim 1 wherein said skin abutting end is abutable against a genital region of a user adjacent to and surrounding said ostium of said user to provide a substantial seal against leakage of urine directed into said body of said device.
12. A mid stream urine device of claim 1 wherein said urine discharge end portion has a tube engaging lug which defines said urine discharge end.
13. A mid stream urine device of claim 12 further comprising a urine collector container and a tube interconnecting said lug and said collector

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container.

14. A mid stream urine device of claim 4 wherein said cap to seal said cap aperture is not removable from said cap aperture after engagement therewith and said container has a tamper indicator to indicate whether said container has been opened.

15. A mid stream urine device of any one of claims 1 - 4 wherein said port has a breakable seal.

16. A mid stream urine device of any one of claims 1 - 4 in combination with a breakable seal for sealing said port.

17. A mid stream urine device of claim 3 or 4 wherein said coupling has a breakable seal.

18. A mid stream urine device of claim 3 or 4 in combination with a breakable seal for sealing said coupling.

19. A mid stream urine device of claim 3 or 4 wherein said port has a breakable seal and said coupling has means to break said seal on engagement with said port.

20. A mid stream urine device of claim 3 or 4 wherein said coupling has a breakable seal and said port has means to break said seal on engagement with said coupling.

21. A mid stream urine device for use by a standing, sitting, squatting or generally supine male to direct a urine stream a satisfactory distance away from said male and for collecting a mid stream urine sample from said stream, said device comprising:

a body having a discharge passage therethrough for receiving and discharging said stream from an ostium urethrae externum masculinae said body having:

a urine stream receiving portion defining one end of said passage, disposed in a penis receiving end operatively coupled to or integral with

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said body;

a urine stream exit portion defining the other end of said passage, disposed in a urine discharge end portion operatively coupled to or integral with said body; and

a mid stream sampling port disposed intermediate to said receiving portion and said exit portion of said discharge passage.

22. A mid stream urine device of claim 21 further comprising a cap adapted to seal said port.

23. A mid stream urine device of claim 21 further comprising a urine sample container having a container coupling engagable with said port.

24. A mid stream urine device of claim 21 further comprising:

a urine sample container;

a cap to engage said container said cap having an aperture and a container coupling engagable with said port operatively associated with said cap aperture; and

a cap to seal said cap aperture before and after use.

25. A mid stream urine device of claim 21 further comprising:

a urine sample container having a container coupling engagable with said port;

a cap to seal said container; and

a urine valve operatively associated with said container coupling wherein on opening said valve a mid stream urine sample of said stream passes from said discharge passage into said container via said port.

26. A mid stream urine device of claim 23, 24 or 25 wherein said sample container has a air release valve disposed on top of said container for releasing air as said container fills with urine.

27. A mid stream urine device of claim 21 wherein said discharge passage has a urine deflector disposed therein so as to deflect a portion of urine

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flowing through said discharge passage into said port.

28. A mid stream urine device of claim 25 wherein said urine valve is integral with said container coupling.

29. A mid stream urine device of claim 28 further comprising a coupling tube operatively associated with said valve to interconnect said urine valve and said port.

30. A mid stream urine device of claim 28 wherein said body has a thread coupling in the immediate vicinity of said port and said urine valve has a complementary thread coupling whereby said valve is threadably couplable to said body whereby to communicate with said port.

31. A mid stream urine device of claim 21 wherein said skin abutting end is abutable against a genital region of a user adjacent to and surrounding said ostium of said user to provide a substantial seal against leakage of urine directed into said body of said device.

32. A mid stream urine device of claim 21 wherein said urine discharge end portion has a tube engaging lug which defines said urine discharge end.

33. A mid stream urine device of claim 32 further comprising a urine collector container and a tube interconnecting said lug and said collector container.

34. A mid stream urine device of claim 24 wherein said cap to seal said cap aperture is not removable from said cap aperture after engagement therewith and said container has a tamper indicator to indicate whether said container has been opened.

35. A mid stream urine device of any one of claims 21 - 24 wherein said port has a breakable seal.

36. A mid stream urine device of any one of claims 21- 24 in combination with a breakable seal for sealing said port.

37. A mid stream urine device of claim 24 or 25 wherein said coupling has

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a breakable seal.

38. A mid stream urine device of claim 23 or 24 in combination with a breakable seal for sealing said coupling.

39. A mid stream urine device of claim 23 or 24 wherein said port has a breakable seal and said coupling has means to break said seal on engagement with said port.

40. A mid stream urine device of claim 23 or 24 wherein said coupling has a breakable seal and said port has means to break said seal on engagement with said coupling.

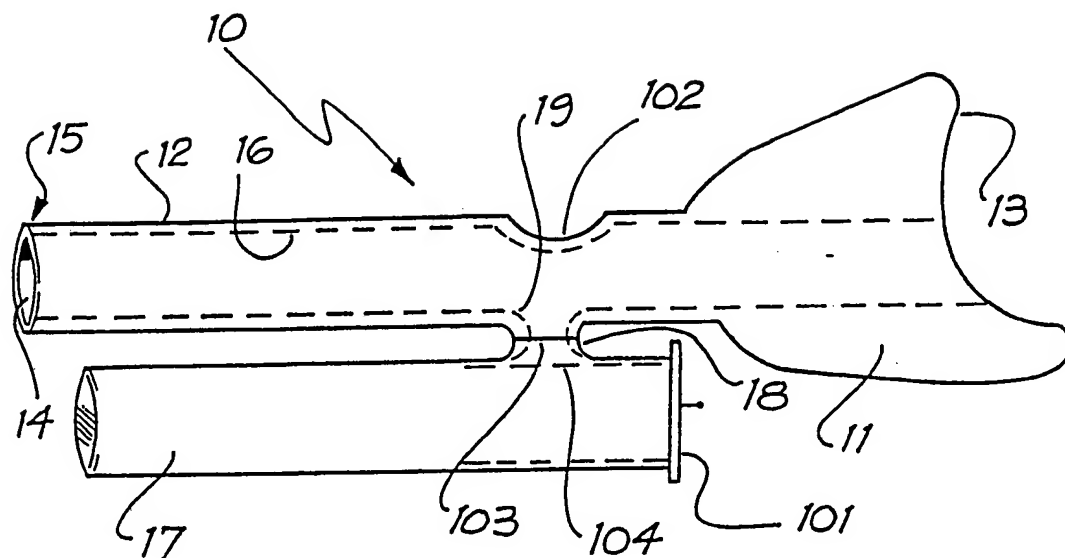


FIG. 1

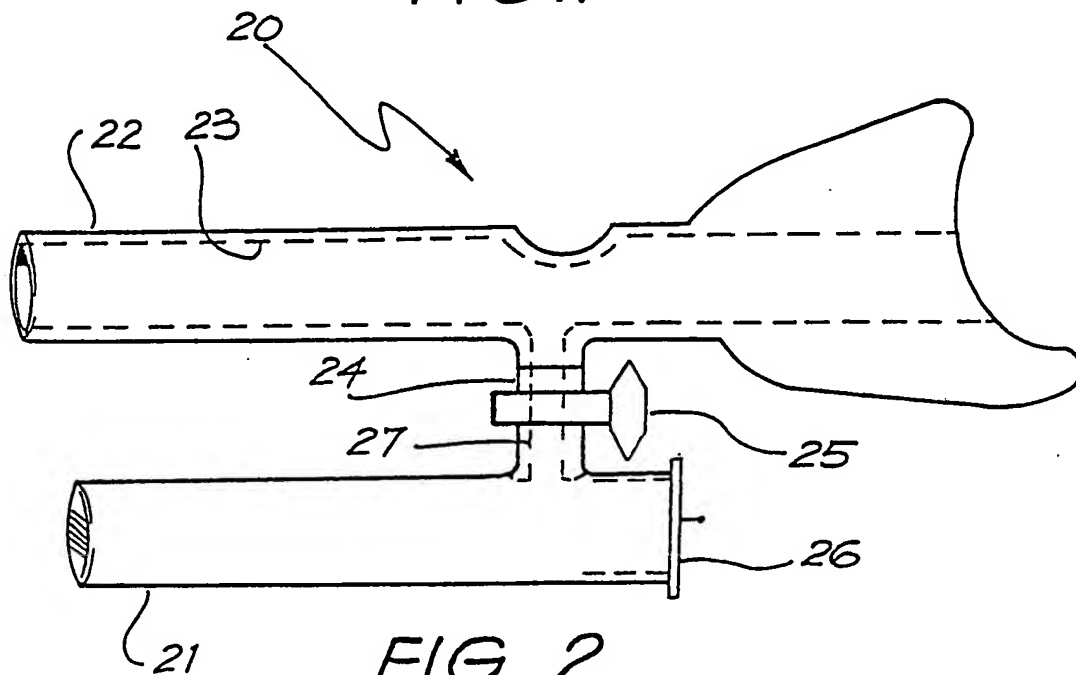
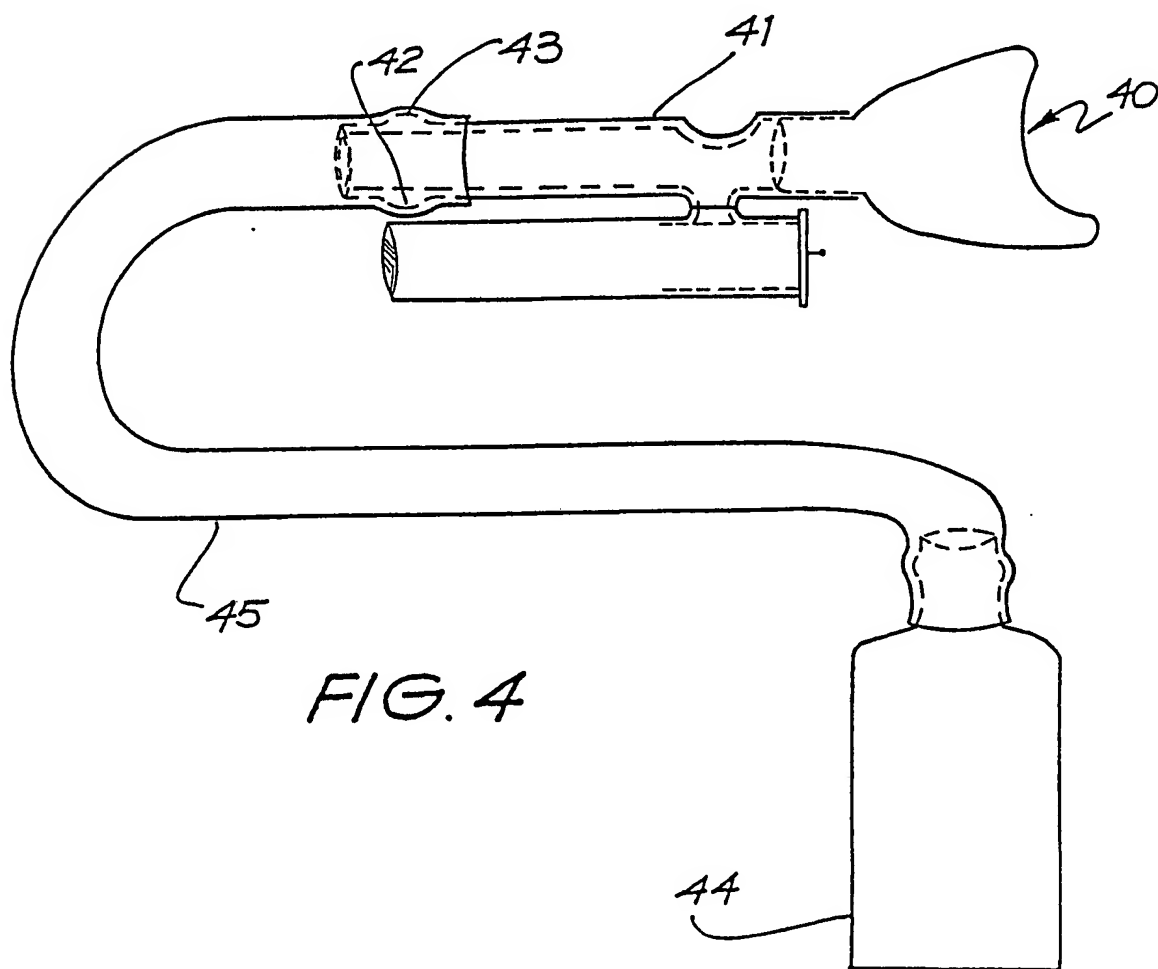
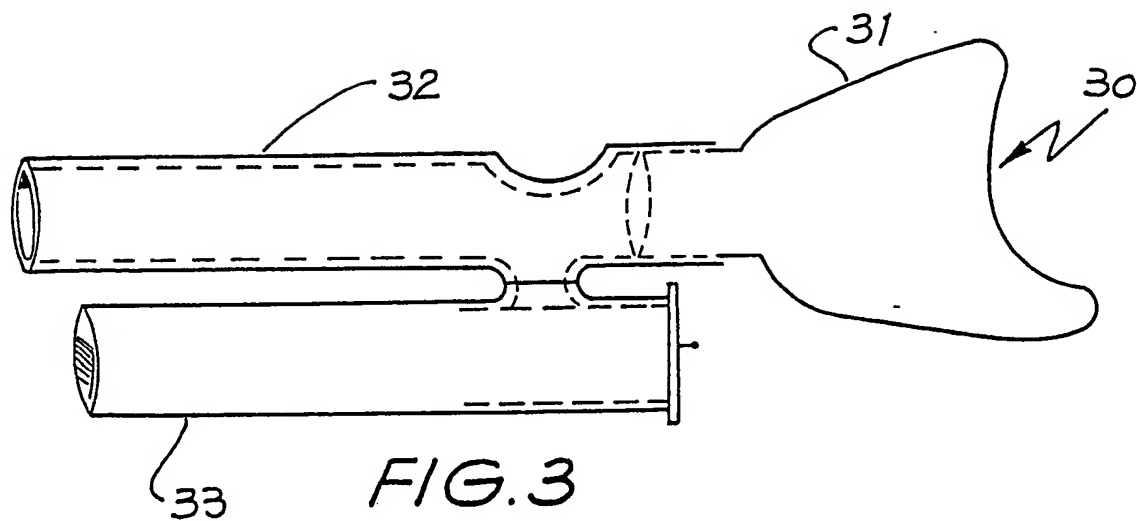


FIG. 2





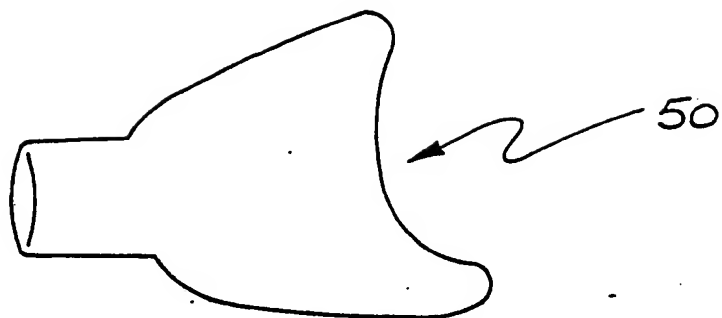


FIG. 5

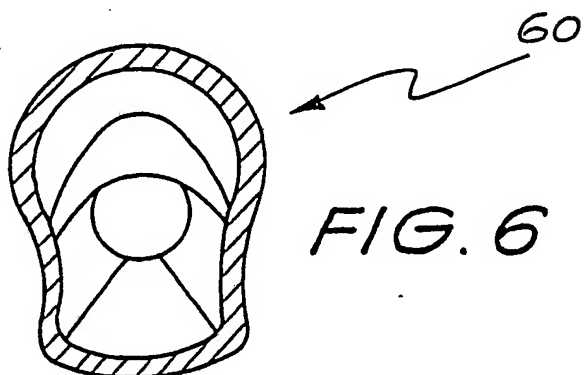


FIG. 6

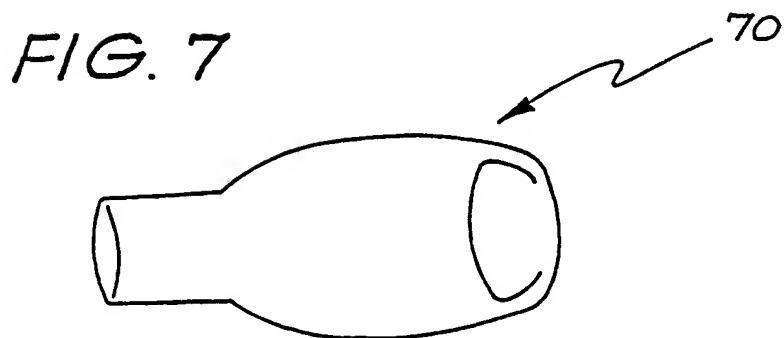


FIG. 7

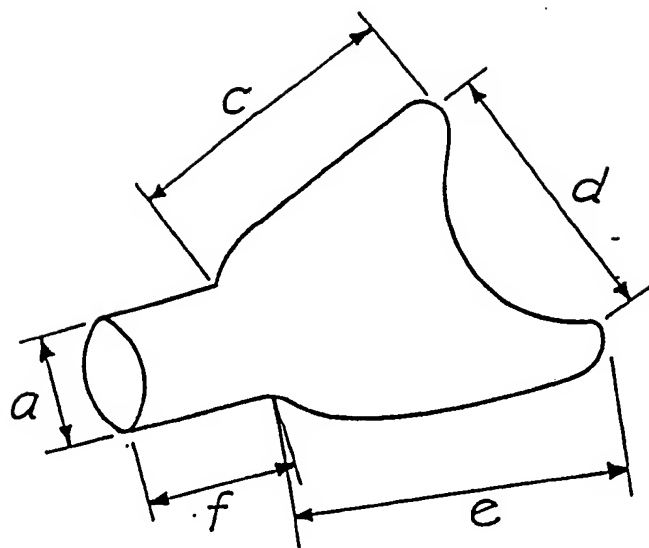


FIG. 8a

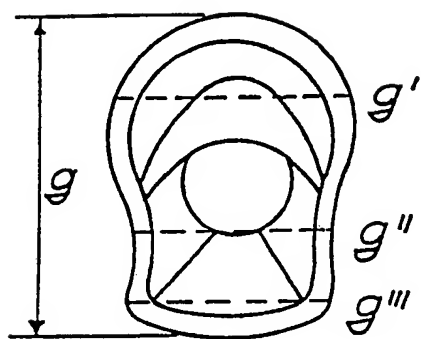
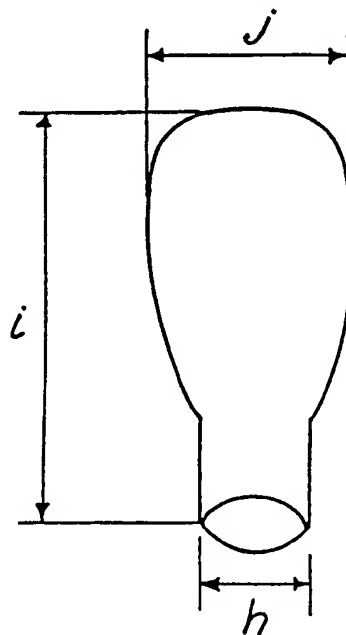
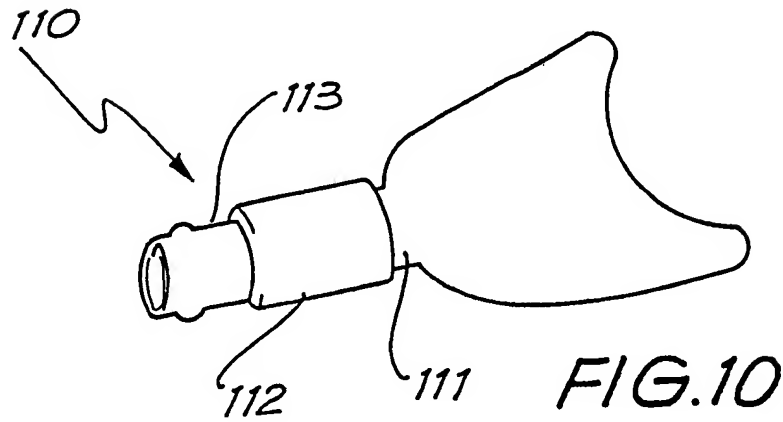
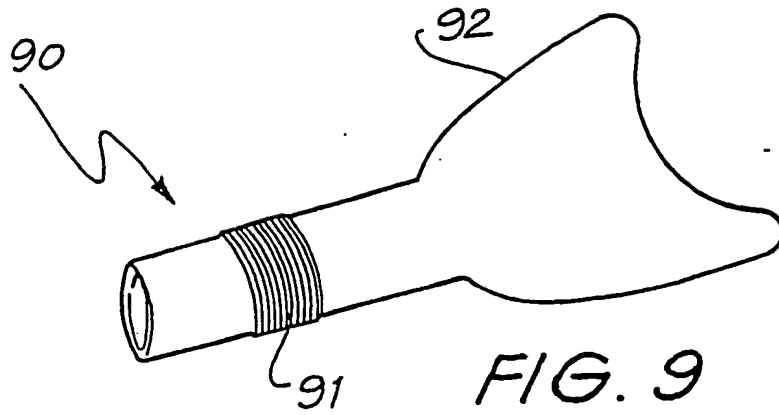


FIG. 8b

FIG. 8c





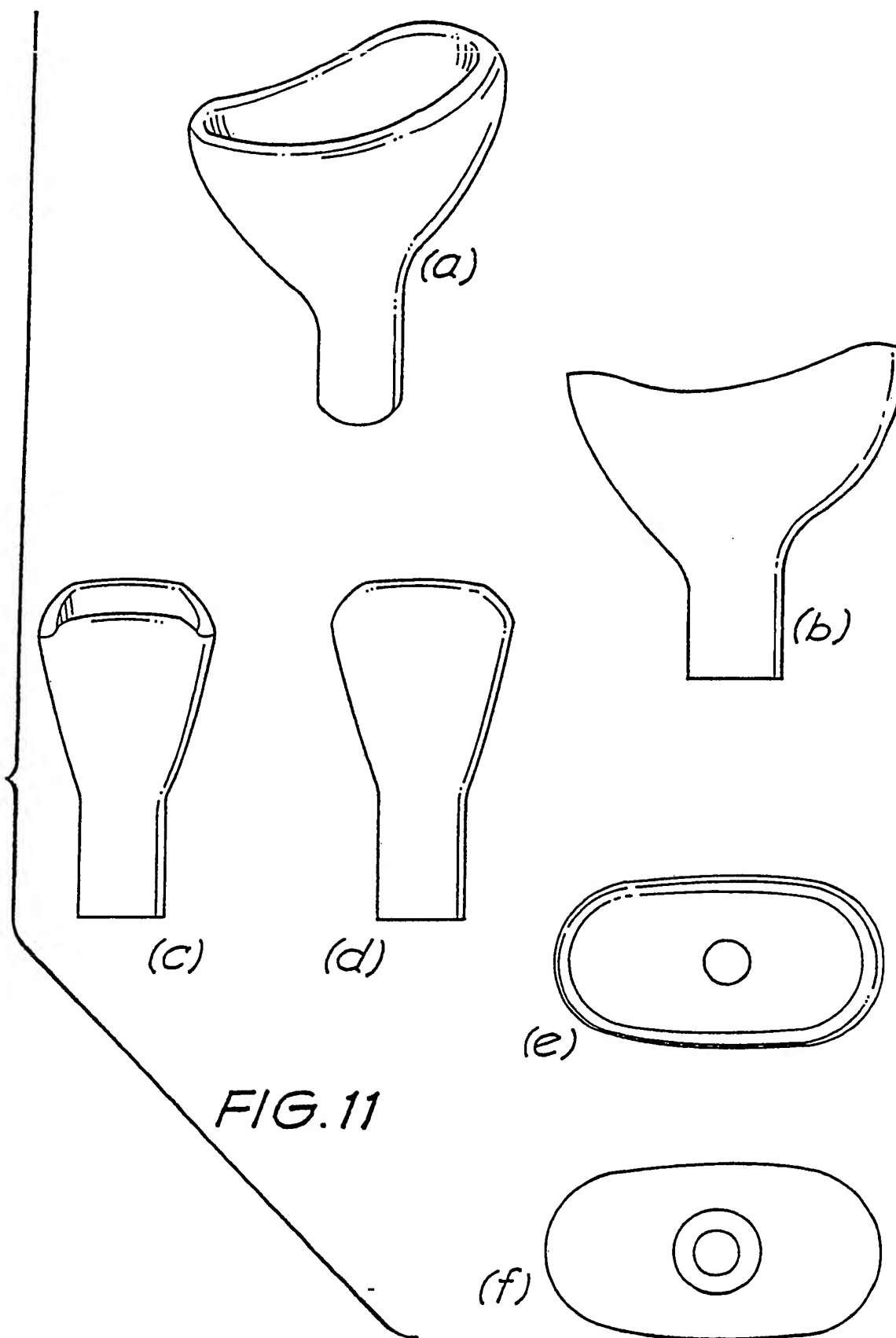
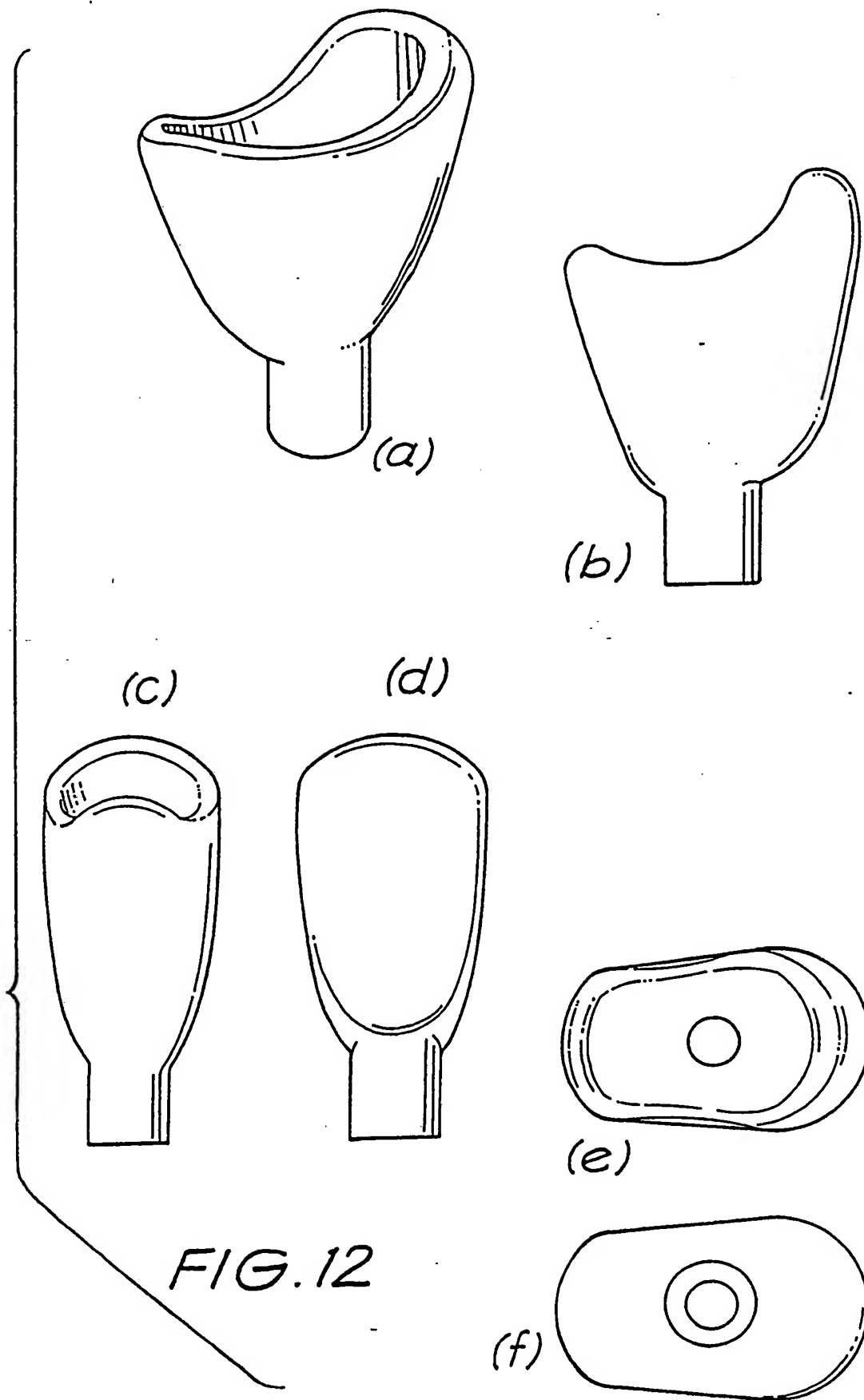
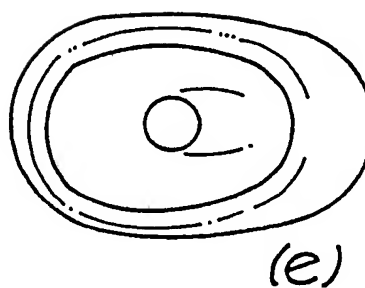
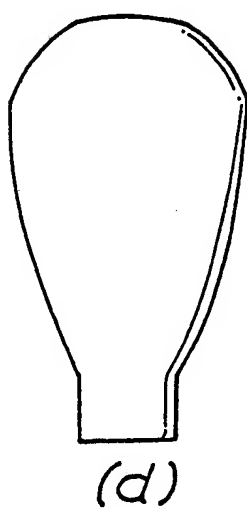
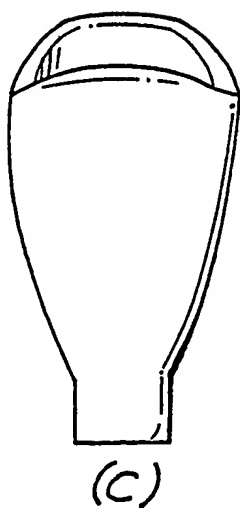
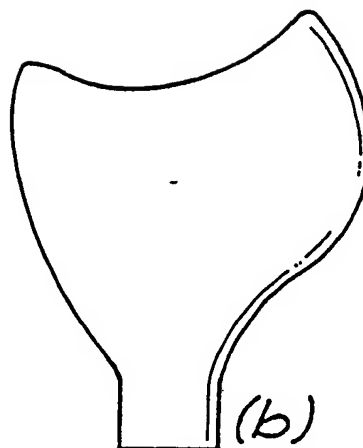
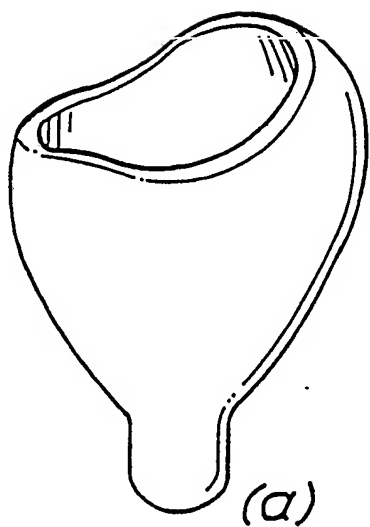


FIG. 11





(f)

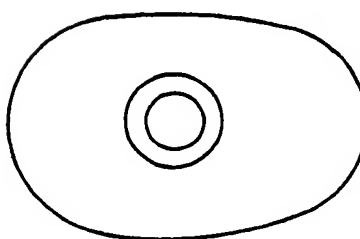
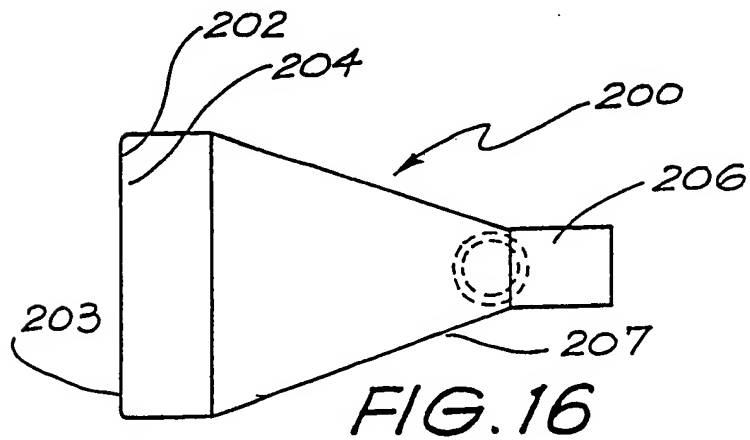
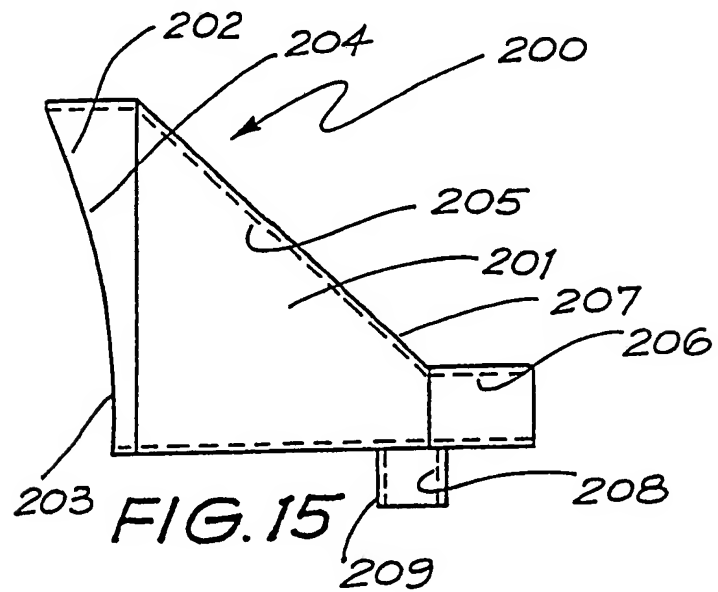
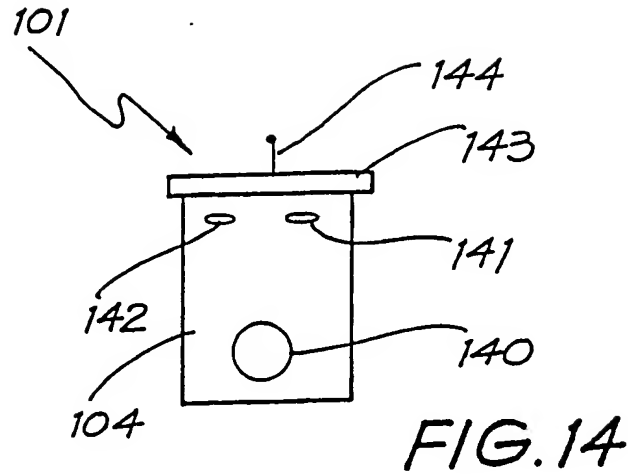
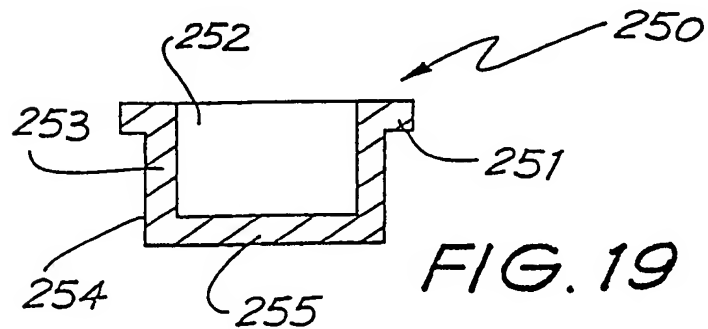
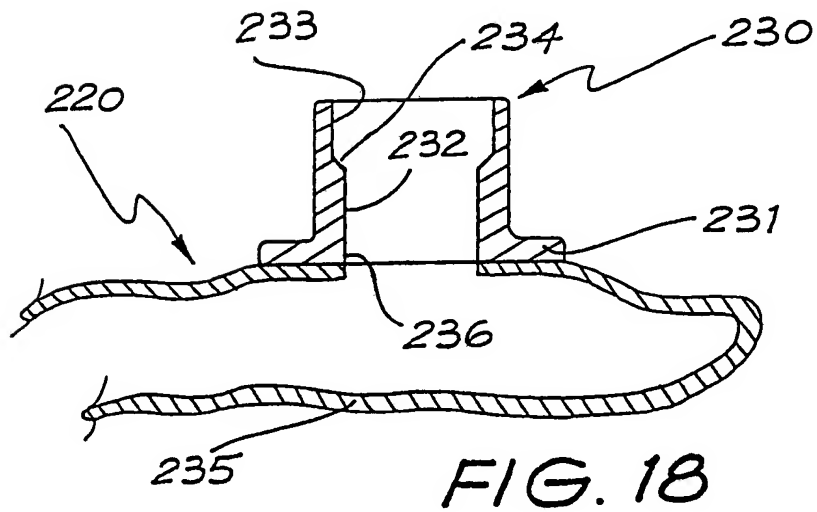
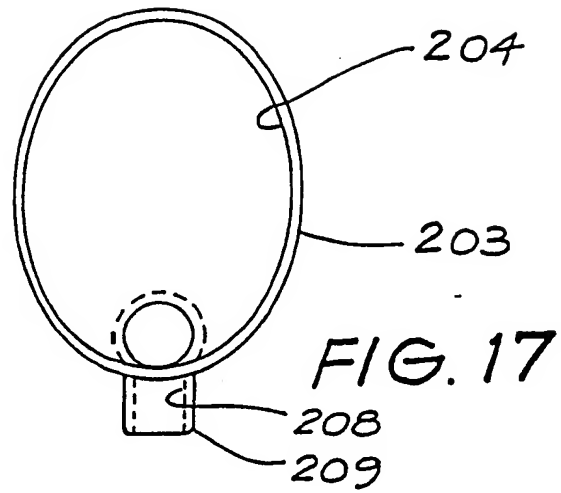


FIG. 13

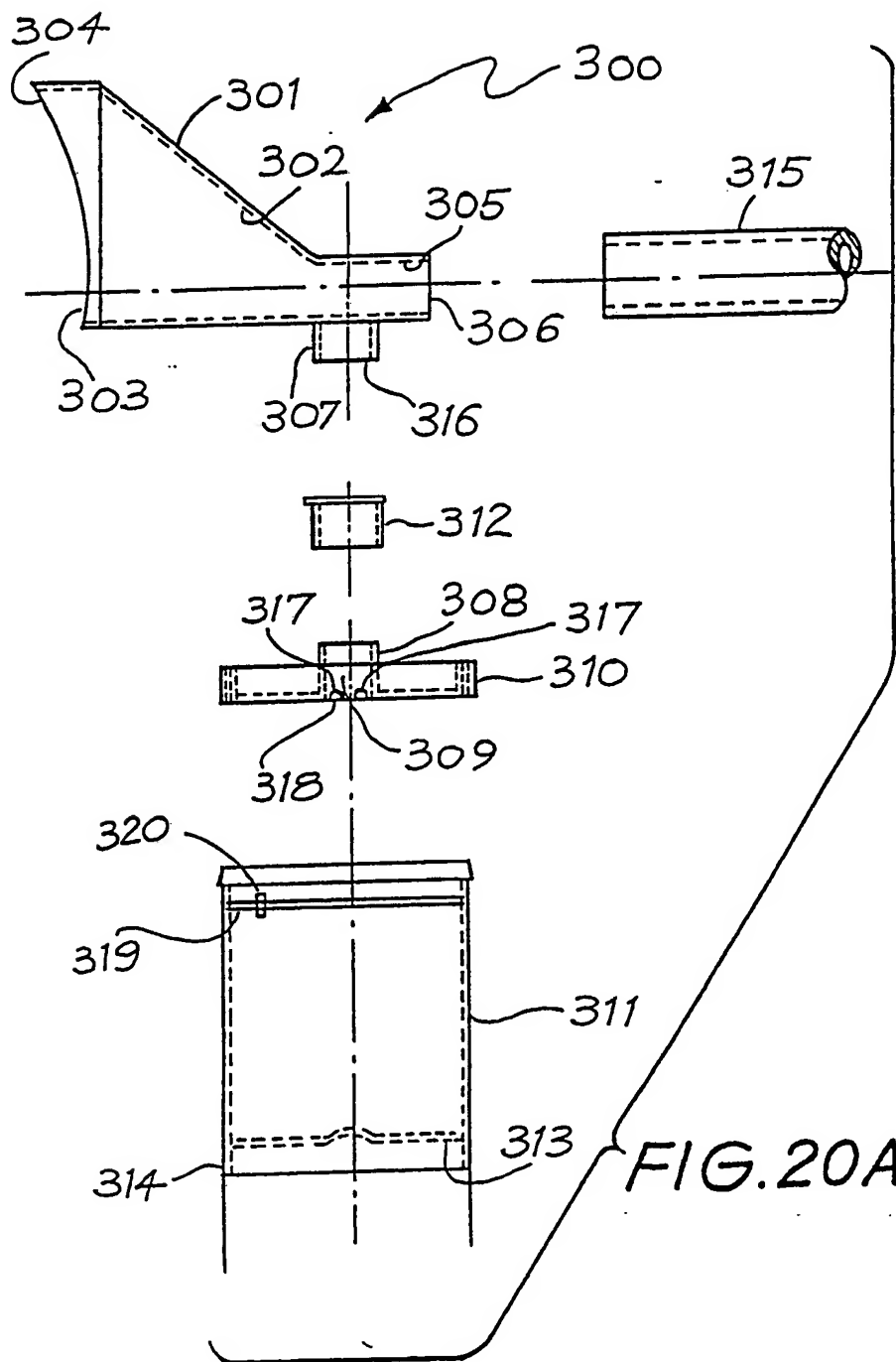
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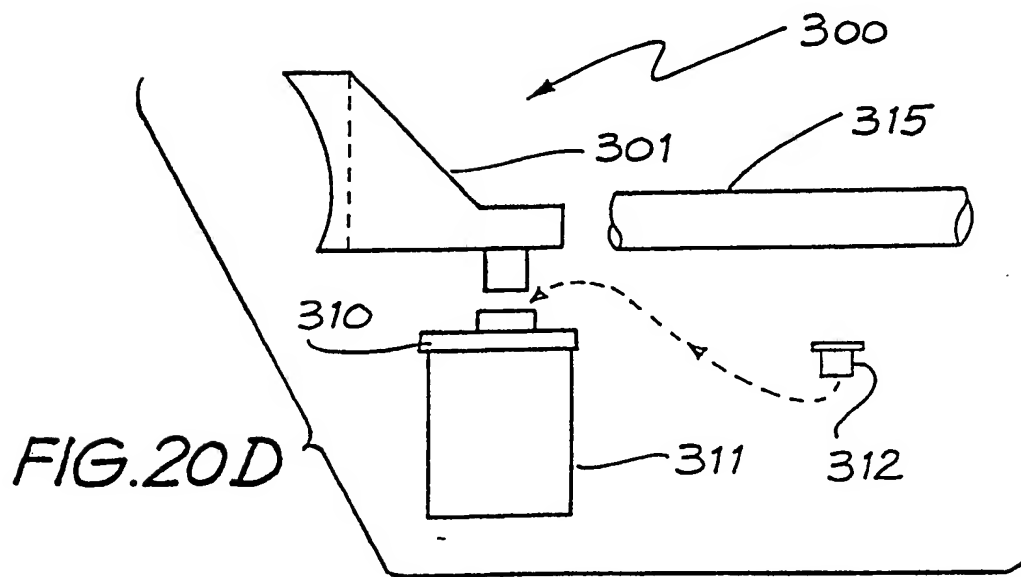
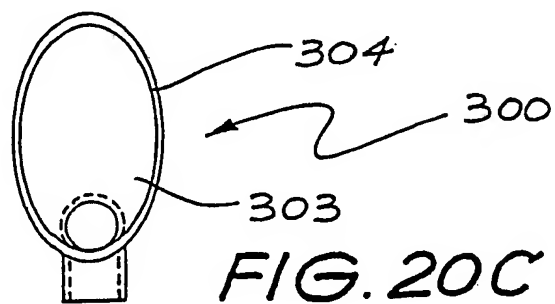
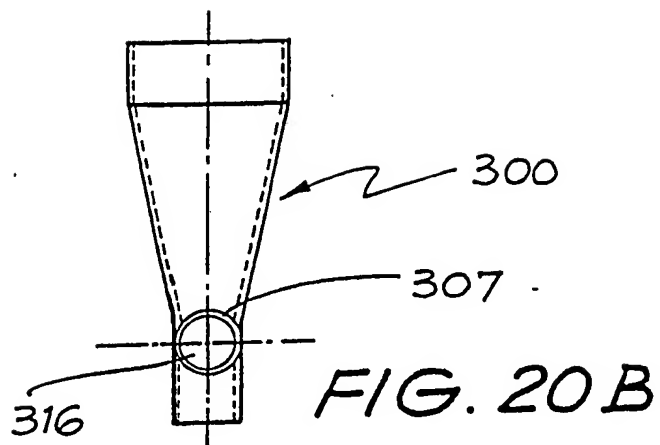


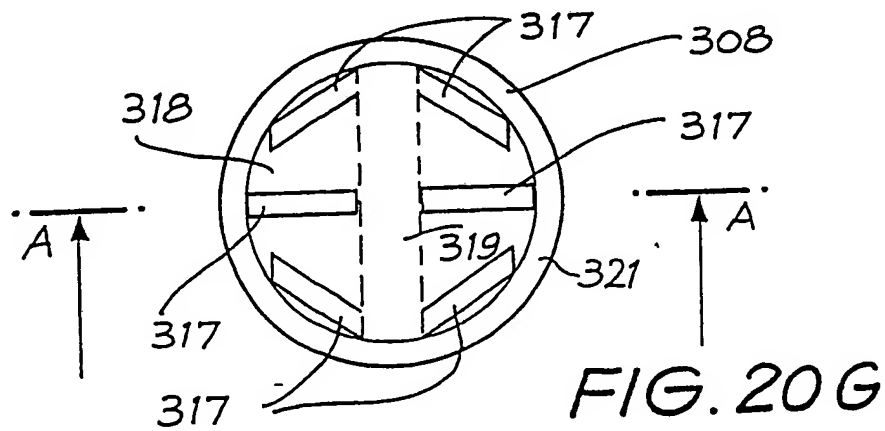
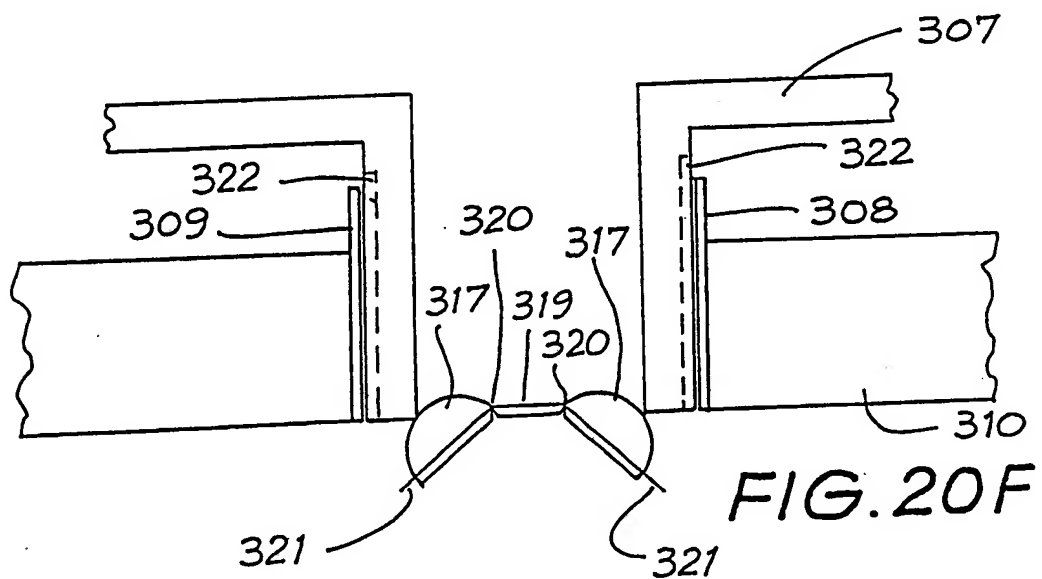
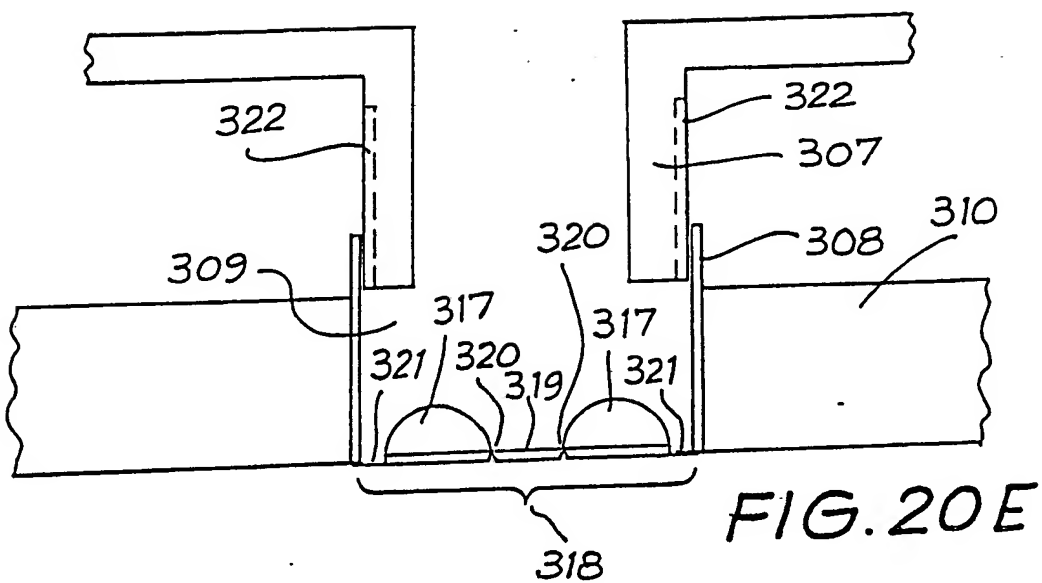
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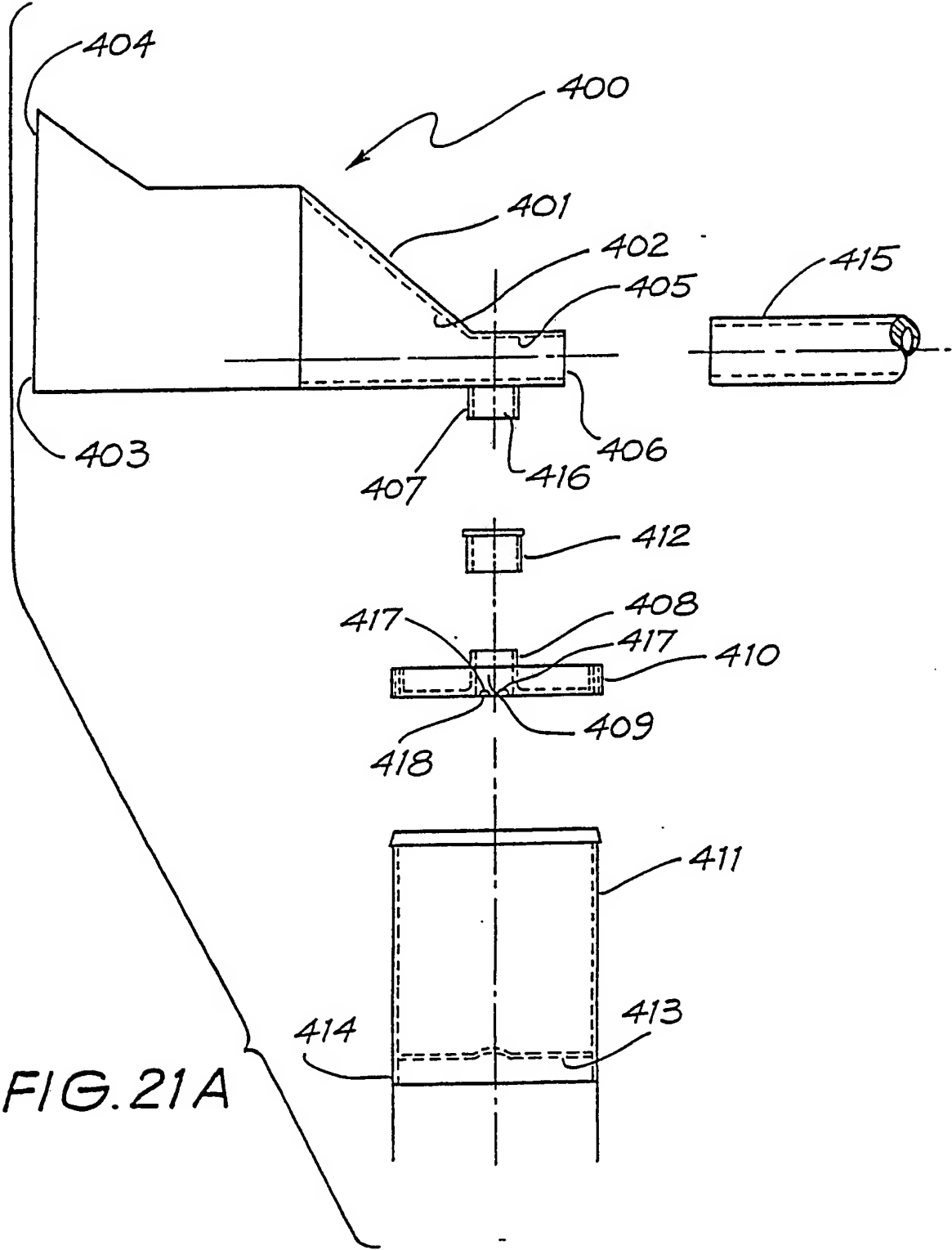


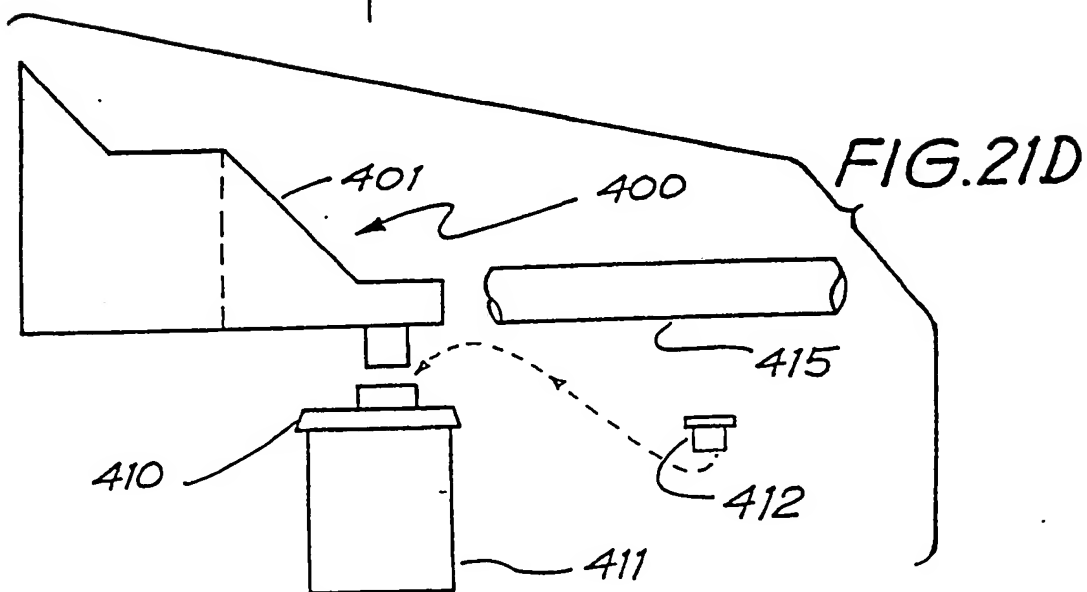
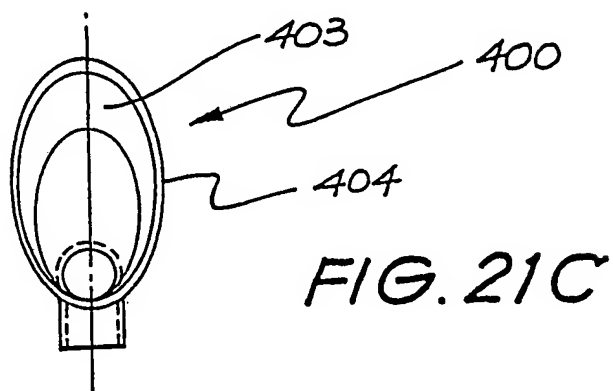
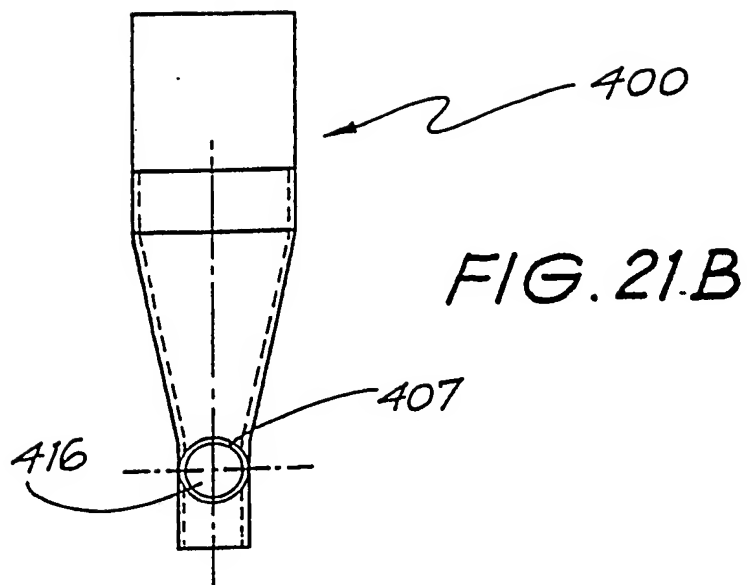


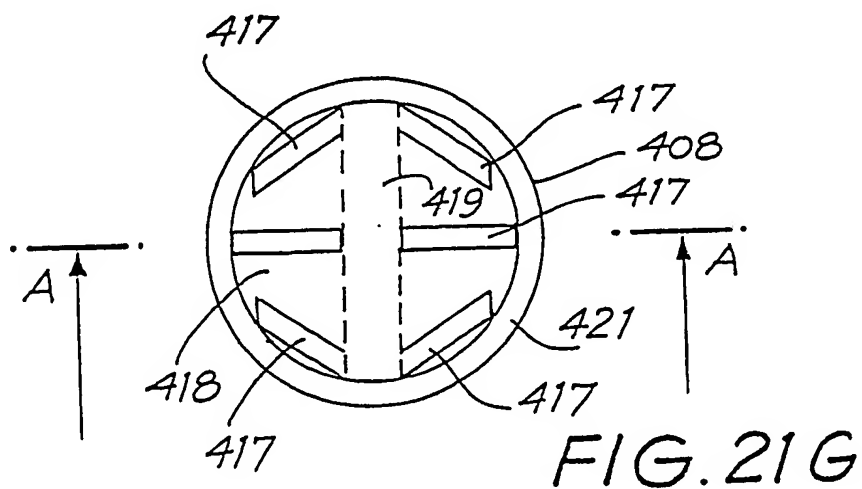
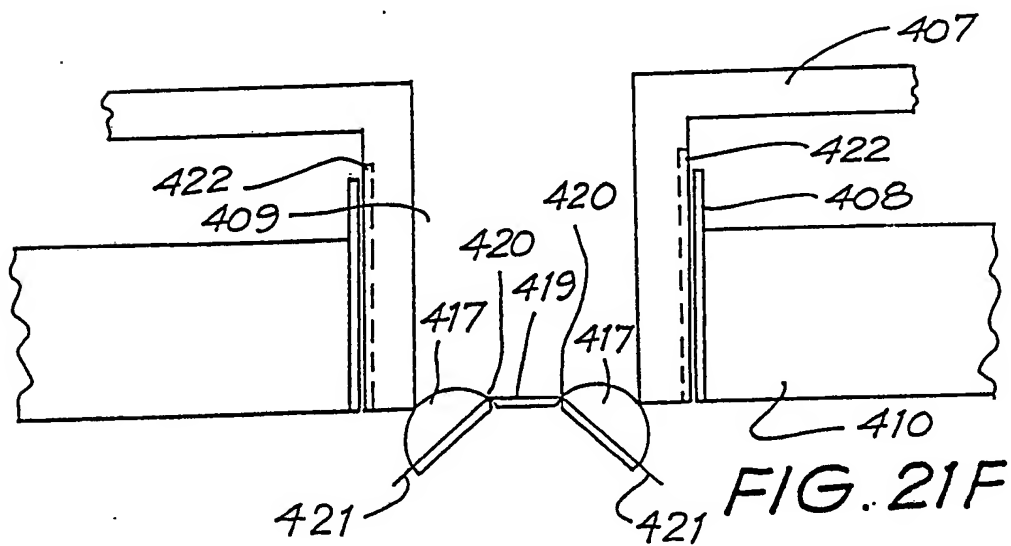
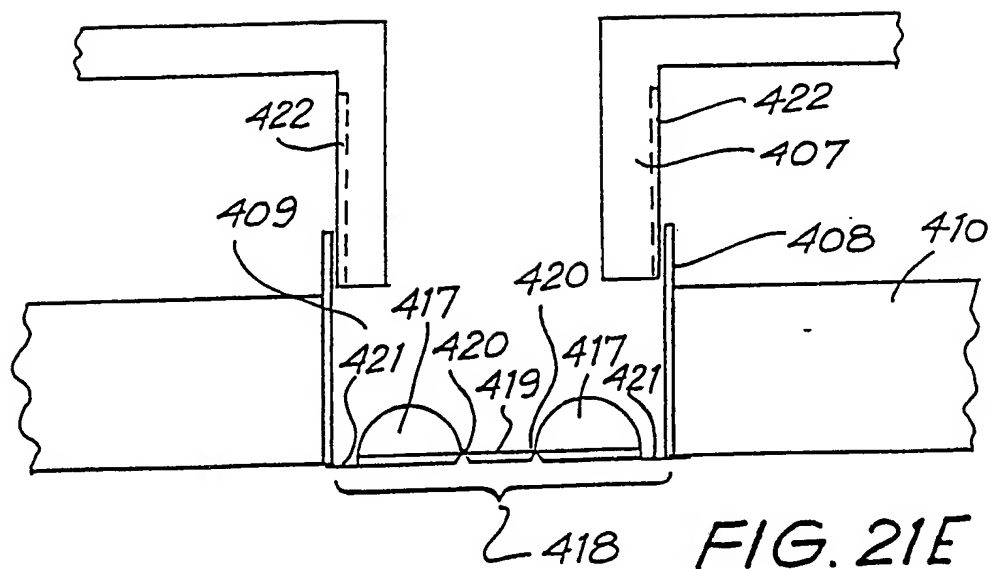






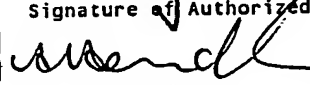






# INTERNATIONAL SEARCH REPORT

International Application No. PCT/AU 90/00169

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) 6		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl. <sup>5</sup> A61J 1/05		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched 7		
Classification System	Classification Symbols	
IPC	A61F 5/453, 5/455, A61J 1/05, A61G 9/00, A61B 5/20	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched 8		
AU: IPC as above		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> 9		
Category*	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages 12	Relevant to Claim No. 13
X	GB,A, 2162312, (CASWOOD) 29 January 1986 (29.01.86), figure 1	(1-40)
X	US,A, 4276889 (KUNTZ et al) 7 July 1981 (07.07.81), figures 1-10	(1-40)
X	US,A, 4040791 (KUNTZ) 9 August 1977 (09.08.77) figures 1-6	(1-40)
X	US,A, 3943770 (McDONALD) 16 March 1976 (16.03.76) figure 3	(1-40)
Y	WO,A, 86/03394 (THE VICTORIA UNIVERSITY OF MACHESTER) 19 June 1986 (19.06.86) figure 1	(1-21)
<p>* Special categories of cited documents: 10</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Z" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search 1 August 1990 (01.08.90)	Date of Mailing of this International Search Report 8 August 1990	
International Searching Authority Australian Patent Office	Signature of Authorized Officer  A. HENDRICKSON	

## III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category*	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
Y	US,A, 4050103 (NAKAO et al) 27 September 1977 (27.09.77) figures 1, 6, 7	(1,21)
Y	US,A, 3830107 (LINZER et al) 20 August 1974 (20.08.74) figure 5	(1,21)
Y	US,A, 3635091 (LINZER et al) 18 January 1972 (18.01.72) figure 7	(1,21)
A	US,A, 3832738 (KLIEMANN) 3 September 1974 (03.09.74)	
A	US,A, 3499327 (LANE) 10 March 1970 (10.03.70)	



ANNEX TO THE INTERNATIONAL SEARCH REPORT ON  
INTERNATIONAL APPLICATION NO. PCT/AU 90/00169

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Members			
<hr/>					
GB	2162312				
<hr/>					
US	4276889	AU 51507/79	BR 7906506	CA 1144840	
		DK 4232/79	EP 9980	ES 484907	
		FI 793120	IL 58414	JP 55076929	
		KR 8301983	MX 149055	NO 793225	
		NZ 191792	PL 223373	PT 70301	
		US 4331162	CA 1121178	US 4252132	
		YU 2449/79	ZA 7905433		
<hr/>					
US	3943770				
<hr/>					
WO	8603394	EP 243360			
<hr/>					
US	4050103	GB 1563343	SE 7612531	SE 8001245	
		JP 52076992	JP 52078513	JP 52076831	
		JP 52083239	JP 52111605	JP 52111220	
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US	3830107				
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US	3635091				
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US	3832738				
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US	3499327				
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